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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,914	02/11/2004	Gerhard Schmid	SCHMID, G. ET AL.-1	3052

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,914	SCHMID ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 05/14/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of IDS filed on 05/14/2004 is acknowledged.

Claims 1-15 are pending and claims 1-15 will be examined on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 10 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a food having an alpha-cyclodextrin content that causes the food to be useful for the risk reduction of an ailment selected from the group consisting of hyperlipidemia, hypertension, obesity, artherosclerosis, diabetes, and the manifold pathological consequences of these conditions, does not reasonably provide enablement for preventing the reduction of an ailment selected from the group consisting of hyperlipidemia, hypertension, obesity, artherosclerosis, diabetes, and the manifold pathological consequences of these conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. To

prevent is to keep from happening.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1).Nature of the Invention:

The rejected claim(s) 10 and 15 are drawn to an invention which pertains to (1) A food having an alpha-cyclodextrin content that causes the food to be useful for the prevention or risk reduction of an ailment selected from the group consisting of hyperlipidemia, hypertension, obesity, artherosclerosis, diabetes, and the manifold pathological consequences of these conditions. Applicant's specification does not discuss or show with data how the recurrence in the reduction of an ailment selected from the group consisting of hyperlipidemia, hypertension, obesity, artherosclerosis, diabetes, and the manifold pathological consequences of these conditions has been kept from happening.

(2).State of the Prior Art:

The skilled artisan would view that the prevention of an ailment selected from the group consisting of hyperlipidemia, hypertension, obesity, artherosclerosis, diabetes, and the

manifold pathological consequences of these conditions is highly unlikely.

(3).Relative Skill of Those in the Art:

The relative skill of those in the art is extremely high.

(4).Predictabilitv of the Art:

The prevention of an ailment selected from the group consisting of hyperlipidemia, hypertension, obesity, artherosclerosis, diabetes, and the manifold pathological consequences of these conditions is highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See In re Fisher, 427 F.2d 833,839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5).Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated. The claims encompass the food having an alpha-cyclodextrin content that causes the food to be useful for the prevention or risk reduction of an ailment selected from the group consisting of hyperlipidemia, hypertension, obesity, artherosclerosis, diabetes, and the manifold pathological consequences of these conditions. Applicant's specification does not discuss or show with data how the recurrence in the reduction of an ailment selected from the group consisting of hyperlipidemia, hypertension, obesity, artherosclerosis, diabetes, and the manifold pathological consequences.

(6).Direction or Guidance Presented:

The guidance given by the specification as to the process for the production of food

used in preventing the reduction of an ailment selected from the group consisting of hyperlipidemia, hypertension, obesity, artherosclerosis, diabetes, and the manifold pathological consequences of these conditions of the instant invention is not disclosed.

(7).Working Examples:

The working examples in the specification to show how the process for the production of food used in preventing the reduction of an ailment selected from the group consisting of hyperlipidemia, hypertension, obesity, artherosclerosis, diabetes, and the manifold pathological consequences of these conditions of the instant invention is not disclosed. Note that lack of a working example to prevent, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

(8).Quantity of Experimentation Necessary:

The specification fails to provide sufficient support of process for the production of food used in preventing the reduction of an ailment selected from the group consisting of hyperlipidemia, hypertension, obesity, artherosclerosis, diabetes, and the manifold pathological consequences of these conditions. Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidance, and the lack of working examples discussed above, a person of skill in the art would not be able to fully practice the instant invention without undue experimentation.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7, 10 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "other physiological or medical disorders'. This limitation is not clear as to what applicant means by disorders. Medical disorders include conditions such as nausea, vomiting, abdominal pain, bleeding sepsis fever etc. Since the invention is drawn towards the effect of alpha-cyclodextrin , such physiological conditions have not been shown to have any correlation with any medical disorder or physiological disorder. Similarly in claim 10 and 15, it is not clear as to what pathological consequences of various diseases the applicant is referring too. It is unclear whether the limitation in parenthesis is indeed the limitation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Artisa et al. (US Pg Pub No. 2005/0019375 A1).

Artisa et al. discloses a composition and method that relate to fat containing consumable food products comprising .alpha.-cyclodextrin. The food products have reduced levels of bioavailable fat but have substantially the same fat, cholesterol and caloric content as a like food without .alpha.-cyclodextrin. The invention also relates to methods for reducing the bioavailability of fats in fat containing food products without reducing caloric intake as determined by bomb calorimetry and to methods for increasing high density lipoproteins in a subject and reducing or controlling weight by administering the food products comprising alpha cyclodextrin (abstract).

Artisa et al. discloses that the total cyclodextrin in the foods is less than about 9-10% w/w, preferably less than about 6%, and more preferably below 3% w/w, and particularly in the case of fat containing consumable farinaceous food products, the amount of total cyclodextrin is below about 3% w/w. The .alpha.-cyclodextrin composition that is used in the products and methods is a substantially pure .alpha.-cyclodextrin comprising at least about 95% .alpha.-cyclodextrin, preferably at least 98% .alpha.-cyclodextrin . Artisa et al. further discloses that the consumable products comprising alpha- cyclodextrin are a dairy food product, a prepared vegetable product, or a prepared meat product, e.g. a prepared beef, lamb, pork, poultry or seafood food product. The consumable food products are suitable for consumption by mammals, e.g., mice, rats, cats, dogs and humans but preferably humans (page 4, [0023]).

The consumable food product is a diet food that inhibits the rate of weight gain, promotes weight loss and provides other health benefits (page 4, paragraph [0024]). Artisa et al. further disclose that by ingesting alpha.-cyclodextrin in an appropriate amount with a fat-containing meal, or shortly before or after ingesting a fat-containing meal, a subject may complex the ingested fat and inhibit its absorption by the body (page 5, paragraph [0028]).

8. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (JP 6-094912).

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (JP 6-094912).

Suzuki discloses that aplpha- cyclodextrin and the composition with alpha –cyclodextrin as the major component have specific biological effects. One of such effects is that of a low calorie carbohydrate, having effective actions of body weight gain suppression and body weight reduction and the second effect is suppression of blood triglyceride concentration at a low level by inhibiting liver triglyceride accumulation.(page 6, paragrapgh 2). Alpha cyclodextrin and its composition helps in treatment of obesity and is important in treatment of hypertriglycemia, arteriosclerosis and triglyceride acuumulative fatty liver (page 6, paragraph2). Suzuki discloses administering alpha-cyclodextrin containing composition to a subject and the alpha-cyclodextrin is present in the composition in amounts of 10-40% (Examples 1-5 and page 7 of the translation); the

alpha-cyclodextrin can be used in the form of powder, granules, aqueous solution (page 7). Suzuki discloses that alpha-cyclodextrin has an inhibitory effect on body weight gain and is administered food at 12-25g/kg body weight for the total cyclodextrin or at 6-13g/kg body weight for the alpha-cyclodextrin (page 4). Therefore it is apparent that alpha-cyclodextrin inherently reduces the glycemic index of the food comprising alpha cyclodextrin.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McBride (US 2003/0190402) discloses the use of cyclodextrin in the formulation of food products having reduced fat. Courregelongue et al. (US 4,880,573) discloses the use of cyclodextrins to remove cholesterol in fatty substance by complexation of the cyclodextrin wit the cholesterol. Bruzzese et al. (US 5 ,189,149) discloses the production of complexes of polyunsaturated fatty acids with cyclodextrin. Conte et al (US 5,560,950) discloses the use of cyclodextrin to reduce the fatty acid content of frying oils.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S. Kishore, PhD/
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Snigdha Maewall

Art Unit

1615